REMARKS

Applicant thanks the Examiner for the courtesies extended during the interview on September 20, 2007.

Claim 14-19 are pending in the present application including independent claim 14. The claims are generally directed to a flow-through assay device for detecting the presence or quantity of an analyte residing in a test sample. The assay device includes a competitive zone that a contains an antibody immobilized on a porous membrane that is complexed to an antigen containing an optically detectable substance, wherein the amount of analyte within the test sample is determined from a competitive signal and at least one of a first detection signal and a second detection signal. As helpfully suggested by the Examiner, the presently pending claims have been amended to also require that the second antibody is complexed to the antigen containing the optically detectable substance **prior to the application of a test sample to the device**.

Claims 14-16 were rejected under 35 U.S.C. 102(e) as being unpatentable over U.S. Patent Application No. 2005/0170527 (Boehringer et al.). Boehringer et al. is directed to quantitative lateral flow assays and devices. The barrier zone 16a of Boehringer et al. was deemed to anticipate the competitive zone of the presently pending claims. Although it has been stated that the "Boehringer et al. reference does not use the signal that is produced in barrier zone in order to determine the amount of analyte in the test sample"[1], it was nevertheless argued in the Office Action that "because the device of Boehringer et al. contains all of the structural limitations recited in Applicant's claimed device, the device of Boehringer et al. would produce the same signals in each of the zones, which could be used in the determination of the amount of analyte in the test sample." It is respectfully submitted that Boehringer et al. does not teach or suggest a competitive zone that a contains an antibody immobilized on a porous membrane that is complexed to an antigen containing an optically detectable substance, wherein the amount of analyte within the test sample is determined from a

1 See April 10, 2007 Interview Summary.

competitive signal and at least one of a first detection signal and a second detection signal.

Applicants note that a claim is anticipated under 35 U.S. C. § 102 only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. M.P.E.P. § 2131. Boehringer et al. does not indicate that any signal is generated in the barrier zone described therein. Boehringer et al. states that "[t]he barrier zone, whether a labelled analyte analog, or a labelled sbp member complementary to the analyte, serves as a means of preventing a labelled species from migrating further along the matrix unless the analyte concentration exceeds a certain threshold level." Para. [0056]. However, the labelled analyte analog and labelled sbp member complementary to the analyte mentioned in the preceding portion of Boehringer et al. refer to labelled analyte analog or labelled sbp member complementary to the analyte that are initially mixed with the sample. This section does not indicate that labelled analyte analog or labelled sbp member complementary to the analyte are present in the barrier zone of Boehringer et al. Indeed, throughout the specification of Boehringer et al., the barrier zone is consistently referred to as comprising an sbp member complementary to the analyte ("The barrier zone has immobilized therein an sbp member complimentary to the analyte or an analyte analog depending on the assay format being used."). Paras. [0058] and [0072].

Such an interpretation is consistent with the description of Boehringer et al. because "when no antigen is present in the sample, all the labelled antigen will bind to the barrier zone" and "[t]he amount of antibody on the barrier zone must be sufficient to bind all the labelled antigen when antigen is not present in the sample." Para. [0058]. Furthermore, the barrier zone is described as usually being "masked off from view and will not be visible in the test device." Para. [0058]. It would make no sense for such a "masked off" barrier zone to be capable of producing a signal. As such, it is respectfully submitted that Boehringer et al. does not teach or suggest a competitive zone that a contains an antibody immobilized on a porous membrane that is complexed to an antigen containing an optically detectable substance. Thus, the presently pending claims patentably define over Boehringer et al.

Nonetheless, in an effort to expedite prosecution of the present application, independent claim 14 has been amended herewith as helpfully suggested by the Examiner to more clearly indicate that the second antibody is complexed to the antigen containing the optically detectable substance **prior to the application of a test sample to the device**.

It is thus believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner DiRamio is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any additional fees required by this Response to Deposit Account No. 04-1403.

Respectfully requested,

DORITY & MANNING, P.A.

10/1/2007
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